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February 16, 2012



Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with TSCA Section 8(e): Interim Results of a Preliminary Prenatal Developmental Toxicity Screening Study in Wistar Rats with [REDACTED]

Dear Sir/Madam:

[REDACTED] is submitting interim results of a preliminary Prenatal Developmental Toxicity Screening Study in Wistar Rats [CrI:WI(HAN) Charles River, Sulzfeld, Germany] with [REDACTED], conducted by [REDACTED]. The substance is an experimental pesticide.

This rangefinding study was carried out with reference to the requirements of the following guidelines:

- EPA Health Effects Test Guidelines, OPPTS 870.3700: Prenatal Developmental Toxicity Study (Aug 1998)
- OECD Guideline for Testing of Chemicals 414: Prenatal Developmental Toxicity Study (22 Jan 2001)

The test substance was administered by gavage to 10 presumed pregnant female rats/group at doses of 0, 50, 100 and 200 mg/kg body weight/day. The duration of treatment was from gestation day 6 through 19. On gestation day 20, the females were necropsied and the weights of the unopened uteri were determined. Contents of the uterus and fetuses were not examined.

The following is a summary of the most relevant results:

At the 200 mg/kg bw/d dose level, food consumption was reduced (14-24%) during the treatment (GD 6-19). The net body weight gain was significantly below control (-52%) from GD 6 onwards, which resulted in reduced carcass weights at the end of the study (10% below control).

At the 200 mg/kg bw/d dose level, vaginal hemorrhage was observed in 4/10 females, along with reduced uterine weights (about 5% below control).



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[XXXXXXXXXX] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures